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Applicants: Dr. Rudolf Falk
Dr. Samuel S. Asculai
(Now assigned to
Hyal Pharmaceutical Corporation)

Title: THE USE OF HYALURONIC ACID OR ITS DERIVATIVES TO ENHANCE DELIVERY OF ANTINEOPLASTIC AGENTS

Inventors: Dr. Rudolf Falk,
Dr. Samuel S. Asculai

Examiner: Dr. Jacqueline Krikorian Ph.D. (*formerly* Dr. Stephen Martin, Ph.D.)

Group Art Unit: 1806 Extended Due Date: September 5, 1996

The Commissioner of Patents
UNITED STATES PATENT OFFICE
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DECLARATION OF IAN CONSTABLE
under § 1.132

I, IAN CONSTABLE, make oath and say as follows:

1. (a) I completed my medical training at the University of Sydney Australia in 1965. After four and half years as intern and then ophthalmology specialist trainee at Royal Prince Alfred Hospital in Sydney, I moved to the Department of Ophthalmology, Harvard Medical School in Boston on a postgraduate scholarship. From July 1970 until the present, I have been involved

continuously in work with hyaluronic acid. In Boston from 1970 to 1975, I carried out extensive testing of experimental batches of hyaluronic acid at the Retina Foundation where Doctors Balazs and Swann had developed methods for its extraction and purification. My role was to test batches in monkeys for inflammatory reaction. This work resulted in several publications in those years and culminated in the commercial success of hyaluronic acid as a viscoelastic injection into human eyes, as an adjunct to surgery. Hyaluronic acid is still widely used for this purpose throughout the world today.

In 1975, I returned to Australia to my current position as Professor and Chairman of Ophthalmology at the University of Western Australia. Since 1975, I have used hyaluronic acid continuously for clinical eye surgery and have from time to time carried out experiments in tissue culture and animals, as well as carried out contract research for two United States based developers of hyaluronic acid, in the 1980's. I have lectured widely on the properties and uses of hyaluronic acid in ophthalmology throughout the world since that time.

It was not until 1990 that I became aware of the studies in cancer patients by Doctors Falk and Asculai and the possible targeting of commonly used drugs in cancer and other conditions by hyaluronic acid. To my detailed knowledge no one had previously published or spoken about the use of hyaluronic acid as a drug delivery agent, which would actually target damaged tissue and therefore have the capability of delivering active drug to the site. During the years 1983 to 1989, I was a member of the central Committee of the Australian National Health and Medical Research Council and was extremely actively involved in the assessment of medical research and its funding in all fields outside of ophthalmology. With my long term interest in hyaluronic acid, it is quite unlikely that its use in the way proposed by Falk and Asculai, if proposed or published by others, would have escaped my attention. When I became aware of

the findings of Doctors Falk and Asculai in 1990, I initiated discussions with Doctor Asculai which lead to my arranging of clinical trials for a number of medical applications in Australia and to the subsequent development of Hyal Pharmaceutical Australia Limited, a publicly listed company for which I agreed to stand in as Chairman.

Now shown to me and marked as *Exhibit 1* is a copy of my curriculum vitae. The reader will note the number of publications relating to hyaluronan that were authored and co-authored by me. As a result of my extensive experience, I consider myself to be an expert in respect of Hyaluronan.

(b) I have, as an expert in respect of hyaluronan, assisted Hyal Pharmaceutical Corporation, the Assignee of the above-identified patent application in the U.S. Patent Office. As a consultant, I was involved in advising Hyal Pharmaceutical Corporation in all aspects of hyaluronan and have carried out research and development and testing for Hyal Pharmaceutical Corporation and an Australian subsidiary company of Hyal Pharmaceutical Corporation for which I am Chairman. I would not, however, let my acting as a Consultant for Hyal Pharmaceutical Corporation or for anyone or my being Chairman of the Australian subsidiary, interfere with or cloud my professional objectivity and responsibilities in executing any declaration for any person.

(c) I have had extensive experience with respect to the use of HA particularly starting in 1970 when I first injected HA into the eyes of animals. No one, prior to 1990-91, thought of using HA as an adjunct for drugs except as a material to "make material (drugs) stick to the eye" in the form of eye drops. This proposal is discussed when I refer to U.S. Patent 4,736,024. This proposal to make the "material" stick was for the purposes of increasing the surface contact time of the dos ge with ie eye for a prolonged period (than was known when the drug was

administered in saline) so that the medicine could leach from the film and be absorbed by the eye. The hyaluronic acid, when applied topically for example to the eye, permitted a slow release of a substance carried by the hyaluronic acid for absorption by the eye proximate the application of the formulation. The hyaluronic acid would increase the contact time with the cornea, and permit the substance carried by the tear film to leak therefrom and be absorbed by the local area to which it contacts. There was no teaching of delivery and transport.

(d) Prior to about 1989, I was also aware that Hyaluronan (hyaluronic acid) had been used for intra articular injections at very high molecular weights (over 2,000,000) for administration to the intra articular cavity to prevent cartilage degradation of the joint.

(e) Thus, by the late 1980's, hyaluronic acid had been proposed to be used as a vehicle for substances which was to provide a retard effect for the release of the substance. The substance was then absorbed for use. There was no active contribution by hyaluronic acid to the transport or delivery of the substance other than by being a carrier of the substance from which the substance leaked. The substance was absorbed when released by the hyaluronic acid The substance was not transported or delivered by the hyaluronic acid to any sites in need of treatment.

2. In or about 1990/1991, I became aware of an invention of Drs. Falk and Asculai which had determined that dosages comprising hyaluronic acid having at least a minimum specified amount of forms of hyaluronic acid having specified molecular weights did in fact transport and deliver medicines and therapeutic agents to sites of diseases and conditions in need of treatment, and for example with respect to the treatment of cancer were obtaining impressive results in patients that were terminally ill. This finding totally surprised me.

This finding was totally unexpected having regard to the state of the art with respect to hyaluronic acid I have since that time learned that Drs. Falk and Asculai's development has been incorporated in the patent application, International Application No. PCT/CA 90/00306, published under International Publication No. WO 91/04058 and which has entered the national phase, I am advised by Ivor Hughes, counsel to Hyal Pharmaceutical Corporation, in the United States Patent Office under Application No. 07/675,908. I have been advised by the said Ivor Hughes that the said United States Application 07/675,908 has been assigned to Hyal Pharmaceutical Corporation. I have been given a copy of International Publication No. WO 91/04058 and have been asked to give my comments with respect to the teachings thereof.

3. This document confirms my understanding of the development I learned of in the early 1990s referred to in paragraph 2.

4. I have examined International Publication No. WO 91/04058 and have determined that the invention in my opinion disclosed therein relates to dosages (dosage amounts) containing hyaluronic acid or salts thereof together with the medicine in effective amounts. The hyaluronic acid and salts thereof are present in varying doses from 10 mg/70 kg person to 1000 mg/70 kg person with optimal doses tending to range between 50 and 350 mg per 70 kg individual discussed at page 26, line 32 to 35. The molecular weights of the form of hyaluronic acid used in the dosages are from 150,000 daltons to less than 750,000 daltons. One amount of hyaluronic acid is a 2% solution with a mean average molecular weight of about 225,000 daltons referred to at page 29 of the application. The dosages of the medicine or therapeutic agent may be known amounts as would be understood by persons skilled in the art or a dose excess where in excess of 200 mg of the form of hyaluronic acid is present in the dosage form. See page 25, lines 20 and line 34 where the in excess amount of 200 mg of hyaluronic acid per 70 kg person is used

in the dosage form. In the dosage administered to the patient, the side effects of, for example an NSAID, are decreased (see page 25, line 22), such as gastro-intestinal distress, neurological abnormalities, depression, etc. By administration of the dosages to patients in need of treatment for the conditions or diseases suffered by the patient, the hyaluronic acid alters the medicine's distribution and performance in the human body and produces an unusual targeting for underperfused tissue and pathological tissue, (page 24, lines 15 to 17). Subsequent experience and testing has confirmed this fact.

5. (a) In my opinion, persons skilled in the art reading the application would understand the Drs. Falk and Asculai had not developed a new medicine/therapeutic agent, but rather enhanced the ability of known medicines and therapeutic agents (and medicines and agents which will become known in the future for use with a specific disease) to reach the sites in need of treatment because in fact the hyaluronic acid targets the site in need of treatment and delivers the medicine/therapeutic agent to the sites of the disease and condition.

5. (b) The inventors have found that when traditional drugs are mixed with hyaluronan as discussed above and administered to patients, the hyaluronan delivers the drugs to the site in need of treatment. This effect has been demonstrated in the Application, on a number of patients, some with incurable cancer, and other with other conditions. When I was first advised of this invention, as I previously indicated, I was surprised that it worked. No one, prior to 1989, thought of using hyaluronic acid except as an adjunct to make the material stick to the eye in the form of the drops. To me, the results achieved by Drs. Falk and Asculai were unexpected. The inventors had even injected intravenously high doses of hyaluronan per day (in some cases, several grams per day), without any adverse effects on the patients. It is, therefore, clear to me that the invention disclosed in International Publication No. WO 91/040508 is

new, useful, and inventive. In fact, the teachings of International Publication WO 91/04058, in my opinion, to persons skilled in the art would enable persons skilled in the art to utilize the invention disclosed with minimal adjustment for individual cases which can be adjusted up or down depending on the benefits provided to the patient. Persons skilled in the art would have no trouble choosing the suitable amount of hyaluronic acid as the hyaluronic acid would be diluted for use in the dosage amounts with most often sterile water to form a small percentage thereof such as indicated at page 29, line 30 (a 2% solution with a mean average molecular weight of about 225,000 daltons).

6. Since the development of the invention, we have learned more about the mechanism of operation and action of the dosages and discovered that the liver and the sites of the disease or condition possess substantial unfilled receptors for hyaluronic acid, whereas normal tissue and cells contain very few unfilled receptors for hyaluronic acid As a result, hyaluronic acid given to the patient targets the underperfused tissue and pathological tissue taking the medicine with it. This ability to deliver and transport the medicine is not disclosed in the prior art. Nor is there any recognition or suggestion of same in the prior art.

7. In my opinion, persons skilled in the art would have no trouble preparing the dosage amounts taught in International Publication No. WO 91/04058 and administering the dosage amounts taught by the application to the patients.

8. Hyaluronic acid occurs naturally as a salt, and particularly it is hard to obtain hyaluronic acid as a non-salt. The expression hyaluronic acid itself already includes hyaluronic acid in salt form as would be understood by persons skilled in the art. The use of the expressions "pharmaceutically acceptable salts of hyaluronic acid", "non-toxic salts of hyaluronic acid" and "salts of hyaluronic acid" would in my opinion be interchangeable having regard to the teachings of

International Publication No. WO 91/04058 and practices in the profession with respect to the treatment of patients. Persons treating patients would only use non-toxic salts and non-toxic amounts of the salts to treat the patients. This is implicit in the teachings in the application.

9. In the treatment of cancer, the cases referred to beginning at page 36 clearly indicate that the patient had been unresponsive to conventional treatment. To me that means that the persons were terminally ill, and that unless the new treatment was successful, the patients would die as a result of the disease. These patients were subsequently treated with the formulations of the invention of International Publication No. WO 91/04058. The patients' conditions improved. Some went into remission.

10. With respect to the molecular weights of the hyaluronic acid used and taught in the application, it is clear that while there may be differences with respect to the extremes of molecular weights of hyaluronic acid known in the field, those referred to in the application between 150,000 daltons and 750,000 daltons would generally perform in the same way, and persons skilled in the art would do some minor (minimal) adjustments when choosing the form of hyaluronic acid and its molecular weight to achieve the desired dosages. Persons skilled in the art further would not have a concern about the dosages employing the hyaluronic acid, because the molecular weights and concentrations of the hyaluronic acid used as taught in the application are not very viscous in the first place, and such persons would dilute the hyaluronic acid because of the addition of the medicine and the excipients necessary to bring the medicine into the dosage form. As a result, in my opinion, persons skilled in the art would have no difficulties in preparing the dosages taught in the application so that they were easily administered to the patients irrespective of whether the dosages were to be systemically administered or topically administered. If any adjustment

would be required, such adjustments would be minimal and within the competence of the practitioner.

11. I have also examined a copy of an article I was advised by Ivor Hughes, was referred to by the United States Examiner, West et al., 1989. I was familiar with this article before the presentation to me by Ivor Hughes counsel for Hyal Pharmaceutical Corporation, and to say the least, the article is very controversial. In any event, the lower molecular weights of Hyaluronan used in the dosages of International Published Application WO 91/04058 is in the order of about 150,000 daltons, not an amount of concern by West et al.

12. Hyaluronic acid, as well, is not very toxic. Because the blood breaks down the large molecular weight molecules of the hyaluronic acid ~~and because such conditions are very rare,~~ the amount of hyaluronic acid is unlikely at the levels indicated in the application to cause any problems.

13. I have also been asked to comment with respect to spontaneous remission. When dealing with the treatment of patients such as those terminally ill with cancer or AIDS, it is totally appropriate to use historic controls, namely those that if the patient is terminally ill (unresponsive to any known treatment), it is assumed that the patient will die. Hence, the statement at page 36, lines 4 to 6, dealing with the cancer cases, it was expected that the patients would die. Spontaneous remission is a rare occurrence, and has no meaning when dealing with the cancer case studies that were given as examples in the application. The successful treatments were, in my opinion, the result of the treatment, not spontaneous remission.

14. Therefore, it is clear to me that persons skilled in the art would be able, reading International Publication No. WO 91/04058, to duplicate them with

respect to the treatments of diseases and conditions. Persons skilled in the art would have no difficulty in doing so. This is because the invention targets the disease or condition site in need of treatment transporting or delivering the medicine/therapeutic agent to the underperfused tissue and pathological tissue. By providing this targeting of the medicines to the site in need of treatment, I believe that the targeting effect enables the reduction of the side effects of medicines/therapeutic agents, for example NSAIDS. Thus, the at least 200 mg of hyaluronic acid targets the site with, for example the NSAID, which may have side effects (not the desired effect) of the medicine such as gastro intestinal distress, neurological effects, etc. which do not materialize because of the targeting effect. While an example is given at page 53 (Case XIX) where the patient suffered heartburn, taking in excess of 300 mg of indomethacin dissolved in 300 mg of hyaluronic acid and the amount was reduced to 100 mg, both the 300 mg and 100 mg are excess dosage amounts of the indomethacin NSAID. Effects on different patients will be different. In case XIX, there appears to have been a heartburn in the patient which was caused by the excess dosage amount of 300 mg which was reduced to the excess dosage amount of 100 mg. In case XVIII, 300 mg of indomethacin was given to the patient in 300 mg of hyaluronic acid, and there appears to have been no problems with the patient taking 300 mg of indomethacin in 300 mg of hyaluronic acid It is therefore clear that the side effects are reduced, that the patient who suffered heart burn taking 300 mg of indomethacin suffered from side effects which were probably still considerably less and probably were considerably less than those that would be normally suffered by such person taking of the excess dosage amount of 300 mg of indomethacin without hyaluronic acid. It is also clear from the teachings of the International Publication No. WO 91/04058 that persons using the drug for the treatment of a disease/condition which has now been targeted by putting the drug into a dosage form with hyaluronic acid, know what side effects are usually exhibited by the drug and are being reduced. In my opinion, persons skilled in

the art would have no difficulties formulating the dosages as taught by International Publication No. WO 91/04058 or administering the dosages in a treatment for treating the disease or condition for which the medicine or therapeutic agent is being given.

15. I have also been asked to review four references, namely Della Valle, et al., United States Patent No. 4,736,024; Seifter, U.K. Patent No. 769287; Schultz, United States Patent No. 4,808,576; and Balazs, hyaluronic acid, Its Structure and Use, Polymers in Chemistry, 1984, Volume 99, pages 65 to 72.

16. Della Valle, United States Patent No. 4,736,024 as discussed in paragraph 1. (c) of my Declaration, teaches the use of hyaluronic acid in dosages including a medicine which do not when administered target the site of a disease or condition. These dosages when applied to the cornea sit there adhering to the surface and do not target anything. The dosages stick to the eye. The medicine is permitted to leech (leak) therefrom, and the Hyaluronan present provides a retard effect. Persons skilled in the art would so understand the teachings of Della Valle, United States Patent No. 4,736,024, and would not think otherwise. Della Valle provides a gel which entraps the medicine and subsequently releases the medicine for absorption on the eye. This is clear from the teachings at column 1, lines 46 to 53, and column 2, lines 44 to 51 of the said reference.

> "When the medicaments are administered in the form of concentrated solutions with elastic-viscous characteristics or in solid form, it is possible to obtain films on the corneal epithelium which are homogenous, stable, perfectly transparent, and which adhere well guaranteeing prolonged bioavailability of the drug thereby forming excellent preparations with a retard effect."

The only examples given are those relating to the topical treatment of the cornea of the eye. In this regard, small amounts of less than 1 mg of hyaluronic acid is to be found in each dosage amount. This is clear from reading column 27, line 57 (micro syringe (10 mcl)); column 29, line 30 (micro syringe (10 µl)), column 30, line 37 (1 drop (50 µl)), which are microlitres; column 31, line 52 (3 drops), and column 33, line 23 (2 drops). One statement is very appropriate, that found at column 30, line 65 "Transcorneal penetration of Pilocarpine seems therefore to depend on the capacity of hyaluronic acid to vehicle a drug forming a homogeneous and stable film on the cornea." It is clear to me that the hyaluronic acid assists to provide a film from which the medicine carried in the film of hyaluronic acid leeches (leaks) and which Pilocarpine medicine is then absorbed by the eye. The teachings of Della Valle are directly opposed to the teachings of International Publication No. WO 91/04058.

17. United States Patent No. 4,808,576 (Schultz) teaches the use of hyaluronic acid as a therapeutic agent only. It is administered for the purposes of treating conditions which were known to be treatable by the use of hyaluronic acid only that the administration takes place at a site remote from the site in need of treatment. However, this remote administration of hyaluronic acid topically is not and cannot be effective without the use of a transdermal carrier (see column 6, line 3, and column 12, lines 14-17). Schultz specifically states that the topical application of the sodium hyaluronate without a transdermal carrier was ineffective (column 12, lines 14 and 15). The transdermal carrier preferred is DMSO and is used in the examples. DMSO is the unique molecule which when applied topically carries material with it which is delivered systemically. DMSO is also an analgesic (sodium salicylate, one of the transdermal carriers, is also an analgesic). Thus, the DMSO delivery of hyaluronic acid as the therapeutic agent, wherein the DMSO is analgesic makes all results of topical application more than suspect - the examples are meaningless.

18. Additionally, with respect to systemic administration, only two examples are provided. Example 1 provides the use of hyaluronic acid having a molecular weight of 1.88×10^6 daltons. There appears to be some success. However, Comparative Example 1, beginning at column 13, casts doubt on the effects provided.

19. In any event, Schultz teaches the use of hyaluronic acid wherein the hyaluronic acid is the therapeutic agent and nothing more. Schultz teaches nothing about delivery to persons skilled in the art.

20. Neither Della Valle nor Schultz teach the targeting of anything by the use of hyaluronic acid

21. It would be clear in both Schultz and Della Valle that they cannot and do not target drugs systemically or topically to the areas in need of treatment.

22. Seifter, U.K. Patent No. 769287 clearly provides that partially depolymerized hyaluronic acid (PDHA) works to spread the agent carried thereby (and thus dilutes the agent and spreads it over a larger area), but that hyaluronic acid which has not been partially depolymerized does not work. Thus, there is no recognition of delivery using hyaluronic acid. Having regard to the teachings of Seifter, it is my opinion that PDHA would not transport the medicine to the site of the disease focus or condition focus. PDHA is, at best, a spreading agent; PDHA spreads and dilutes the medicine, not target it.

23. The Balazs article entitled "Hyaluronic Acid: It's Use and Structure" adds nothing.

24. In view thereof, it is my opinion that even if the teachings of the various references are combined (which I do not see possible), the references do not in any way allude to, suggest or in any way teach the targeting of medicines and therapeutic agents by their administration with hyaluronic acid to a site in need of treatment.

25. This targeting by Drs. Falk and Asculai in International Publication No. WO 91/04058 is achieved using dosages containing between about 10 mg and 1000 mg (or more) of hyaluronic acid or a salt, each having a molecular weight between 150,000 daltons and about 750,000 daltons and containing an effective amount of a medicine/therapeutic agent.

26. In summary, therefore, the invention disclosed in International Published Application WO 91/04058 recognizes that dosages can be given to patients whereby the hyaluronan potentiates the effects of the drugs by enabling them to be delivered (transported) to the sites in need of treatment even permitting the use of very high doses of hyaluronan (in some cases, several grams per day without any adverse effects on the patients) was totally unexpected to persons skilled in the art

27. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements will jeopardize the validity of the application and any patent issuing thereon.

EXECUTED this 4TH day of September, 1996.

IAN CONSTABLE

EXHIBIT 1

CURRICULUM VITAE

NAME: Ian Jeffrey CONSTABLE AO MB,BS
FRACO FRACS FRCS(Ed.)
Dip Am.Board Ophthal.

ADDRESS: Centre for Ophthalmology & Visual Science
Lions Eye Institute
2 Verdun Street
NEDLANDS WA 6009
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61 9 383 3486 (Home)

* * *

EDUCATION:

- MB BS University of Sydney, 1965.
- Diploma of American Board of Ophthalmology, 1973.
- Fellow of Royal College of Surgeons, Edinburgh, 1973.
- Fellow of Royal Australian College of Ophthalmologists, 1975.
- Fellow of Royal Australasian College of Surgeons, 1976.

ACADEMIC APPOINTMENTS:

- Research Associate, Eye Research Institute of Retina Foundation, Boston, 1970.
- Clinical Retinal Fellow, Massachusetts Eye and Ear Infirmary, Boston, 1971 - 1972.
- Assistant Scientist, Retina Foundation, Boston, 1973
- Instructor in Ophthalmology, Harvard University, 1974-75
- Associate Scientist, Eye Research Institute of Retina Foundation, Boston, 1974 - 1975.
- Acting Director, Retina Service, Massachusetts Eye and Ear Infirmary, 1974 - 1975.

CURRENT POSITIONS:

- Foundation Lions Professor of Ophthalmology, University of Western Australia, 1975 - present.
- Foundation Director of The Lions Eye Institute, Perth, 1984 - present.

MEDICAL LICENCES:

- New South Wales, 1966.
- Massachusetts, USA, 1973.
- Western Australia, 1975.

HOSPITAL APPOINTMENTS:

- Resident Medical Officer, Royal Prince Alfred Hospital, Sydney, 1966 - 1967.
- Registrar in Ophthalmology, Royal Prince Alfred Hospital, Sydney, 1968 - 1970.
- Retinal Fellow, Massachusetts Eye and Ear Infirmary, Boston, 1971 - 1972.
- Assistant Ophthalmic Surgeon, Massachusetts Eye and Ear Infirmary, 1973 - 1975.

HOSPITAL APPOINTMENTS (continued):

- Consultant Ophthalmic Surgeon, Royal Perth Hospital, 1975 - present.
- Consultant Ophthalmic Surgeon, Sir Charles Gairdner Hospital, 1975 - present.
- Consultant Ophthalmic Surgeon, Fremantle Hospital, 1976 - present.
- Consultant Ophthalmic Surgeon, Hollywood Repatriation Hospital, 1976 - present.
- Consultant Ophthalmic Surgeon, St John of God Hospital, 1976 - present.
- Consultant Ophthalmic Surgeon, Princess Margaret Hospital for Children, 1981 - present.

FEDERAL GOVERNMENT MINISTERIAL APPOINTMENT:

- National Health & Medical Research Council, Canberra, Medical Research Committee, 1984 - 1989.

VICTORIAN STATE GOVERNMENT APPOINTMENT:

- Commissioned by the Government of Victoria to examine and report on the provision of eye, ear, nose and throat services for the state, 1987 - 1989.

BOARD OF DIRECTORS - RESEARCH FOUNDATIONS:

- Ophthalmic Research Institute of Australia, 1976 - 1986.
- Australian Foundation for the Prevention of Blindness (WA), 1976 - present.
- OPSM Charitable Research Foundation Limited, 1979 - 1984.
- Lions Save Sight Foundation, 1976 - present.
- Construction and Industrial Eye Foundation, 1990 - present.
- The Karl Stein Foundation, 1990 - present.
- The Viertel Foundation, 1995 - present.

REVIEWER FOR THE FOLLOWING RESEARCH FOUNDATIONS:

- Ophthalmic Research Institute of Australia.
- OPSM Charitable Research Foundation Limited.
- Construction and Industrial Eye Foundation.
- The Karl Stein Foundation.
- National Health & Medical Research Council of Australia.
- Australian Research Grants Committee.
- Ramaciotti Foundation.
- Australian Repatriation Health Research Foundation.
- Australian Brain Research Foundation.
- American Diabetes Research Foundation.
- Australian Diabetes Research Foundation.
- Victorian Cancer Council.
- Queensland Cancer Council.
- Queensland University Research Institute.

REVIEWER FOR THE FOLLOWING JOURNALS:

- Investigative Ophthalmology.
- British Journal of Ophthalmology.
- Diabetes Research & Clinical Practice.
- Experimental Eye Research.
- Investigative Ophthalmology & Visual Science.
- Journal of Eye Trauma.
- Modern Medicine.

PROFESSIONAL COLLEGE APPOINTMENTS:

- Examiner, Royal Australian College of Ophthalmologists, 1977 - 1985.
- Member, Royal Australian College of Ophthalmologists Qualification and Education Committee, 1977 - 1985.

INTERNATIONAL APPOINTMENTS:

- Senior Vice President Asian-Pacific Academy of Ophthalmology, 1978 - present.
- External examiner, Royal College of Surgeons, Edinburgh
- External examiner, University Malaya and University Kebaangsaan, Malaysia.

AWARDS:

General

- Advance Australia Award, 1980.
- Citizen of the Year, Western Australia (Professions), 1967.
- Officer of the Order of Australia, 1988.

Medical

- Lang Medal, Royal Society of Medicine, London, 1980.
- Crouch Fellowship of Royal Australasian College of Surgeons for Surgical Research, 1987.
- Sir Norman Gregg Medal and Lecture, Royal Australian College of Ophthalmology, 1987.
- De Ocampo Lecture, Asia Pacific Academy of Ophthalmology, 1989.
- John Chang Lecture, Hong Kong Ophthalmological Society, 1989.
- Sir Arthur Sims Commonwealth Travelling Professorship 1994.

OFFICIAL INTERNATIONAL GUEST OR VISITING PROFESSORSHIPS:

1975	Ophthalmological Symposium, Cambridge.
1976	Asia-Pacific Academy of Ophthalmology, Indonesia. Microsurgical Congress, Singapore. Malaysian Ophthalmological Society, Kuala Lumpur.

1977	Alcon Travelling Professor, Bangladesh and Pakistan. Microsurgical Congress, Singapore.
1978	Microsurgical Congress, Singapore.
1979	World Microsurgery Congress, Singapore. Asia-Pacific Academy of Ophthalmology, Karachi. Visiting Fellow, Strangeways Laboratories, Cambridge University (6 months sabbatical leave).
1980	Centennial Meeting Ophthalmology Society of the United Kingdom, London. Lang Lecture, Royal Society of Medicine, London. Annual Congress, Royal Australian College of Ophthalmologists, Christchurch, New Zealand.
1981	Microsurgical Congress, Singapore. Laser and Retinal Meeting, Penang, Malaysia.
1982	International Congress of Ophthalmology, San Francisco - Opening Ceremony Speaker.
1983	Asia-Pacific Academy of Ophthalmology, Hong Kong. Symposium on Outer Retina, Cambridge, UK. International Congress of Medical Epidemiology and Statistics, Paris.
1984	Macula Society, San Diego, USA. University of Illinois, Eye and Ear Infirmary, Chicago. Ophthalmological Society of South Africa. Indonesian Ophthalmological Congress, Yogyakarta.
1985	Asia-Pacific Academy of Ophthalmology, New Delhi, India. Guest Professor University Kebaangsan, Kuala Lumpur, Malaysia. World Health Organisation Expert Committee on Diabetes, Monaco.
1986	Research to Prevent Blindness Visiting Professor, University Southern California, Los Angeles. Chicago Ophthalmological Society.
1987	Japanese Ophthalmological Society, Kyoto. Asia Pacific Academy of Ophthalmology, Kuala Lumpur, Malaysia.

1989	Asia Pacific Academy of Ophthalmology, Seoul, Korea - De Ocampo Lecture. Aegean Retina Symposium, Crete, Greece. Hong Kong Ophthalmological Society - Chang Lecture.
1990	International Congress of Ophthalmology - Singapore.
1991	Asia Pacific Academy Ophthalmology Kyoto - Japan. Ophthalmological Society, Peoples Republic of China - Tianjin China.
1992	Afro Asian Ophthalmological Academy - Jakarta Indonesia.
1993	Aspen Retinal Society, Aspen, Colorado, USA. Hong Kong Ophthalmological Society. Indonesian Laser Society. Tufts New England Medical School, Boston, USA.
1994	Sankara Nethralaya Eye Hospital, India. Lv Trasad Eye Institute, Hyderabad, India.
1995	The 3rd International Research Workshop - Hyal Conference, Switzerland. International Symposium Modern Challenges in Ophthalmology, Hong Kong. Address to Australian Chamber of Commerce, Hong Kong.
1996	Aspen Retina Society Meeting, Aspen, Colorado, USA. Japanese Ophthalmological Society Symposium, Kyoto, Japan. The 4th International Research Workshop - Hyal Conference, Paris, France.

MEMBERSHIP PROFESSIONAL ASSOCIATIONS

- American Academy of Ophthalmology.
- Australian Medical Association.
- Australian Association of Surgeons.
- Australian Society for Medical Research.
- Association for the Research in Vision and Ophthalmology USA.
- Macula Society USA.
- International Society for Eye Research.
- American Society for Lasers in Medicine.
- Schepens International Retina Society.
- Vitreous Society.
- Aspen Retinal Society.
- Australian Diabetes Association.
- Asian Pacific Academy of Ophthalmology.

UNIVERSITY OF WESTERN AUSTRALIA

As Foundation Professor to the Chair of Ophthalmology endowed by the Lions organisation since 1975, I have built a clinical and research unit with major interests in vitreoretinal disease, diabetic retinopathy, biomaterials, excimer and new laser, image analysis, retinal pigment epithelial transplantation, molecular biology and gene therapy and community screening for eye disease. Our department provides comprehensive ophthalmic teaching and referral clinical services to the major teaching hospitals of Perth.

LIONS EYE INSTITUTE, PERTH

As foundation Director since 1984, I have been responsible for the formation, fund raising, commissioning of laboratories and recruiting of over 100 staff for this facility. The Institute has attracted extensive research grants from local, national and international sources. In addition, the Lions Eye Institute has assembled a rapidly growing endowment fund. It is now established as the principal point of referral of major eye disease in Western Australia and attracts many referrals from South East Asia. The Institute has grown in five years to be the largest eye research facility in the Southern Hemisphere. We currently spend about A$6 million per year on Eye Research.

New laboratories commissioned in 1995 are amongst the most modern and best equipped in Australia.

LIONS SAVE-SIGHT FOUNDATION (WA) INC

This Foundation has branches through Lions clubs in every town in Western Australia. As chief advisor to the Board, I have designed and spearheaded statewide fund raising and community screening programmes for glaucoma, amblyopia, trachoma and diabetic retinopathy.

The LSSF has provided several million dollars for eye research and community screening for eye disease in Western Australia.

AUSTRALIAN FOUNDATION FOR THE PREVENTION OF BLINDNESS (WA DIVISION) INC

As Secretary/Treasurer 1976 to the present time, I have been responsible for the development of the AFPB by private donations from business to the point where its endowment fund has become a major resource for eye research.

THE CONSTRUCTION AND INDUSTRIAL EYE FOUNDATION OF WA INCORPORATED

In 1989, with representatives of unions and major companies, I established a foundation to research and prevent industrial accidents and provide eye care.

INDUSTRIAL RESEARCH AND DEVELOPMENT

I am currently Chairman of Medical Biomaterials Pty Ltd (Perth) and TELCO (Perth), biotechnology and laser companies which have been built on Lions Eye Institute technology.

INDUSTRIAL RESEARCH AND DEVELOPMENT (continued)

In 1987, the Lions Eye Institute was awarded one of eight major national grants for development of new surgical biomaterials by the Federal Department of Industry, Technology and Commerce (Professor Constable, Principal Investigator).

I am Chairman of Hyal Pharmaceutical Australia Limited, a public company listed on the Australian Stock Exchange.

The Lions Eye Institute currently holds syndicate research and development grants for laser technology ($6M) and an artificial cornea ($3M).

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